

were linearly related to PVR (Table) however the highest correlation with the severity of PVR was seen with the maximum diameter ( $r^2=0.48$ ,  $p<0.001$ ), mean diameter ( $r^2=0.47$ ,  $p<0.0001$ ), average diameter ( $r^2=0.48$ ,  $p<0.0001$ ) or the annular area ( $r^2=0.48$ ,  $p<0.0001$ ).

**Conclusions:** This study demonstrates that 3DE measurements of the aortic annulus are feasible and are better predictors of PVR after TAVR than 2D sagittal diameter and should be incorporated into the algorithm for balloon-expandable transcatheter valve sizing.

Comparison of 2DE and 3DE Measurements				
Cover Index	NoPD (n=23)	PD (n=35)	p-value	r <sup>2</sup> for linear measure
2DE Sagittal	10.14 ± 4.02	6.89 ± 3.24	0.002	0.26 (p = 0.001)
3DE Minimum	16.19 ± 6.39	10.88 ± 4.91	0.001	0.36 (p<0.0001)
3DE Maximum	8.67 ± 7.87	-2.74 ± 6.50	< 0.001	0.48 (p<0.0001)
3DE Mean	12.44 ± 6.65	4.07 ± 4.71	< 0.001	0.47 (p<0.0001)
3DE Average	11.50 ± 6.11	2.68 ± 4.93	< 0.001	0.48 (p<0.0001)
3DE Area	23.09 ± 10.32	7.91 ± 9.14	< 0.001	0.48 (p<0.0001)

## TCT-98

### The Impact of Effective Aortic Annulus Sizing by 3D Computed Tomography on Paravalvular Leak Development after Transcatheter Aortic Valve Implantation

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**Background:** Despite excellent outcome after transcatheter aortic valve implantation (TAVI), paravalvular leaks may occur. Objective of this study was to evaluate annulus sizing by 3-D computed tomography (CT) for prediction of paravalvular leaks after TAVI, and to compare CT with transesophageal (TEE) and intracardiac echocardiography (ICE).

**Methods:** In 88 patients (mean, 83yrs) with severe aortic stenosis who underwent TAVI, transesophageal (TEE), intracardiac echocardiography (ICE) and ECG-gated CT-Angiography were performed before device implantation. Two-(ML/AP), three-annulus diameter (RC/LC/NC) and the annulus area were measured on CTA. "Undersizing" was defined as CT annulus-prosthetic heart valve (PHV) size; "annulus eccentricity" as AP/ML-annulus diameter ratio. Post-procedural echocardiography was performed immediately after, and at 1, 3, 6, 12 and 24 month after the procedure and severity of paravalvular leaks graded.

**Results:** Of 88 implanted prosthetic heart valves (PHV) 22 (25%) had none, 46 (52.3%) mild, 11 (12.5%) mild-to-moderate, 9 (10.2%) moderate or moderate-to-severe, and 0% severe leaks. Both TEE and ICE measured smaller mean annulus diameters than CT (mean:-2.84mm and -2.19mm, resp.,  $p<0.01$ ). Overall, 53% of PHV were undersized, in only 3/22 (14%) patients with no leaks and in 35/66 (53%) with leaks. Undersizing was higher in those with leaks as compared to those without (1mm vs. 0.2mm,  $p<0.01$ ). No difference between mild and moderate-to-severe (1mm vs. 1.2mm,  $p=0.64$ ) leaks were found for the mean of 3-annulus diameters. The annulus area undersizing was higher in patients with leaks than in those without (0.44cm<sup>2</sup> vs 0.14cm<sup>2</sup>,  $p<0.05$ ), however the annulus eccentricity index was not different (0.82 vs. 0.82,  $p=0.06$ ). If applying the 3-instead of 2-diameter annular CT measurements, 4 (5%) patients without leaks and 2 (2%) with leaks were reclassified as not-undersized and undersized, respectively.

**Conclusions:** PHV undersizing relative to CT annulus dimensions is associated with paravalvular leaks after TAVI, but not annulus eccentricity. Three-diameter annulus sizing by CT may be more accurate than the two-diameter method.

## TCT-99

### The Vancouver Computed Tomography Sizing Guidelines for Transcatheter Aortic Valve Replacement with Balloon Expandable Valves

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**Background:** To develop computed tomography (CT) sizing guidelines for transcatheter aortic valve replacement (TAVR). CT annular measurements are predictive of paravalvular regurgitation post TAVR; a predictor of mortality and morbidity.

**Methods:** The Vancouver CT sizing guidelines aim to ensure routine transcatheter heart valve (THV) over sizing of the aortic annulus (range:1-20%, target 10-15%). Percentage of over sizing is defined as (THV external area/annular area-1) x 100. 120 consecutive

patients underwent CT prior to TAVR with balloon expandable valves using transesophageal echocardiography (TEE) sizing recommendations. The Vancouver CT sizing guidelines recommended prosthesis size was compared to the actual size implanted.

**Results:** As compared to TEE sizing recommendations, the Vancouver CT sizing guidelines recommended a larger valve in 33.3% (40/120), no change in valve size in 55.8% (67/120) and a smaller valve in 10.8% (13/120). In patients where CT guidelines would have recommended a larger valve, the incidence of at least moderate paravalvular regurgitation was 25% (10/40), compared to only 4.5% (3/67,  $p<0.01$ ) when both TEE and CT guidelines were in agreement. Traditional TEE sizing methods resulted in 33.3%(40/120) of valves being under sized (THV area<CT annular area) with a mean annular over sizing of  $9.4\pm 17.4\%$  (range: -21.5 to 65.9%) without annular rupture. In contrast, the Vancouver CT sizing guidelines results in mean annular over sizing of  $13.9\pm 8.0\%$  (range: 1.3-29.8%).

**Conclusions:** The Vancouver CT sizing guidelines enable standardized moderate over expansion of the annulus that is likely to result in significantly lower rates of paravalvular regurgitation.

## TCT-100

### Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves: Results from the Global Valve-in-Valve Registry

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**Background:** Transcatheter aortic valve-in-valve (VIV) implantation is an emerging therapeutic alternative for patients with failed surgical bioprosthesis and may obviate the need for a redo surgery. We aimed to evaluate the clinical results of this technique using a large worldwide registry.

**Methods:** The registry included 416 patients with degenerated aortic bioprosthetic valves (age  $77.7 \pm 9.7$  years; 55.3% men) from 54 cardiac centers. The mode of failure was stenosis (n=168, 40.4%), regurgitation (n=125, 30%), and combined stenosis and regurgitation (n=123, 29.6%). Implanted devices were Edwards SAPIEN (n=225), CoreValve (n=190) and Melody (n=1).

**Results:** Adverse procedural outcomes included 11.1% device malposition and 1.9% ostial coronary obstruction. Post-procedure, valve maximum / mean gradients were  $28.5 \pm 14.3$  mmHg /  $16.1 \pm 9.0$ , respectively. Independent predictors for high post-procedural gradients (mean  $\geq 20$  mmHg) were baseline bioprosthesis stenosis [vs. regurgitation, odds ratio (OR), 6.33,  $p<0.001$ ] and the use of the Edwards SAPIEN device (OR 2.1,  $p=0.008$ ). At 30-day follow-up, all-cause mortality was 7.8% and 87.5% of patients were at New York Heart Association functional class I/II. One-year survival was 82.6%. The strongest independent predictor for 1-year mortality post VIV was baseline bioprosthesis stenosis (vs. regurgitation, OR 3.7,  $p=0.003$ ).

**Conclusions:** The VIV procedure is clinically effective in most patients, with 1-year results comparable with other TAVR cohorts. Baseline bioprosthetic stenosis is the strongest predictor for both elevated post-procedural gradients and 1-year mortality.

## TCT-101

### 12M Results of a 2nd Generation Transapical Aortic Bioprosthesis for the Treatment of Patients with Severe Aortic Stenosis

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**Background:** A novel, innovative transapical aortic valve implantation (TA-TAVI) system completed enrollment (n=90) in two pre-market studies. The TA device received